www.eubiologics.com

CRM$_{197}$

Diphtheria toxin mutant

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EuBiologics Co., Ltd. is a privately-held Korean biopharmaceutical company providing contract research and manufacturing services to domestic and international clients. In addition to building a portfolio of vaccines designed to improve global public health, the company was established with the objective of becoming a preferred strategic partner providing solutions for the development and manufacturing of biopharmaceutical products.

The company is capable of manufacturing a variety of mammalian cell and microbe-derived, protein based therapeutics and antibodies. It provides customized services to various stages of product development, including cell banking, GMP production, validation and regulatory support.

The company has licensed in the manufacturing technology necessary to produce an oral cholera vaccine from the International Vaccine Institute and worked on the development of a safe and effective oral cholera vaccine, Euvichol for global public market. Euvichol was accredited by obtaining WHO prequalification in 2015.

Our mission is "For health that lasts a lifetime" and the vision is "To be a global biopharmaceutical company providing safety, health and lively future" For additional information about the company, please visit http://www.eubiologics.com/ENG/

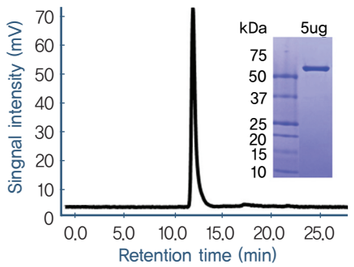
Qualification of CRM_{197}

CRM_{197} is a genetically detoxified form of diphtheria toxin that has been successfully and widely used as a carrier protein for developing carbohydrate conjugated vaccines.

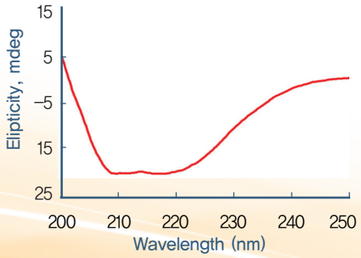
CRM_{197} has also been reported as an anti-cancer factor that binds and inhibits EGF receptor heparin-binding epidermal growth factor-like growth factor (HB-EGF), which is overexpressed in cancer cells.

EuBiologics has established a highly productive CRM_{197} manufacturing process by growing C. diphtheriae in order to use this protein not only for the production of conventional vaccines but also for cancer immunotherapeutics development. The qualification of CRM_{197} was fulfilled through analysis of characteristics (SDS-PAGE, western blot (not shown), SEC-HPLC analysis, circular dichroism and so on).

SEC-HPLC of CRM_{197}



Circular dichroism spectrum of CRM_{197}



CRM_{197} Product Details

- **Native CRM_{197} by C. diphtheriae strain**
- **High yield of CRM_{197}**
- **High purity of CRM_{197}**
- **Not very expensive but high quality**

Source
- Corynebacterium diphtheriae

Species
- Corynebacterium diphtheriae

Product list
- 0.2 mg/vial
- 0.5 mg/vial
- 1.0 mg/vial

Formulation
- Each vial contains 0.2/ 0.5/ 1.0 mg of CRM_{197}, a non-toxic mutant of diphtheria toxin.
- When reconstituted with 1 mL sterile deionized water, the protein is in 1.8 mM sodium phosphate monobasic, 21 mM sodium phosphate dibasic, 5% sucrose, 0.005% polysorbate 80, pH 7.4.

Concentration
- Protein concentration was determined by Bradford assay using bovine serum albumin as the standard.

Purity
- The purity of the product was estimated as > 95% by densitometric and SEC-HPLC analysis.
- The endotoxin content determined using a kinetic chromogenic LAL assay was <1 EU/μg.

Storage
- This preparation is provided as a lyophilized powder. Before reconstitution, it should be stored at 2-8℃ For extended storage, it is recommended to store in aliquots at -20℃ to -80℃
  *NOTE: Repeated freezing and thawing or maintaining the preparation at 2-8℃ for extended periods of time are not recommended.

Use
- Before use, reconstitute lyophilized powder with sterile deionized water to a concentration of 0.2/ 0.5/ 1.0 mg/mL CRM_{197}.
- Handle the product gently, do not vortex. Reconstituted CRM_{197} should be stored at 2-8℃
- **FOR RESEARCH USE ONLY and NOT FOR HUMAN USE.**

References

1. Giannini G et. al., Nucleic Acids Res. 12: 4063-4069 (1984)
2. Malito E et. al., Proc Natl Acad Sci U S A. 109 (2012) 5229-5234
3. Dateoka S et. al., Med Mol Morphol. 45 (2012) 91-97